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DEC 21 2001

510(k) Summary of Safety and Effectiveness SunLase 800P Dental Laser

Applicant: Lares Research
295 Lockheed Ave.
Chico, CA 95973

Contact Person: Thomas H. Louisell
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Date Prepared: 17 May 2001

Device Trade Name: PocketPro or PocketPro S4

Common Name: Nd:YAG Pulsed Laser

Classification Name: Instrument, Surgical, Powered, Laser (79-GEX)

Legally Marketed Predicate Devices:
American Dental Technologies - PulseMaster™
American Dental Technologies - DioLase ST™
BioLase Technology, Inc. - TwiLite™
CeramOptec - Ceralas® D15
Dentek Laser Systems - LD-15™
OpusDent, Ltd. - Opus 10™
Premier Laser Systems - Aurora™
Xintec Corporation - Dentica™

Device Description: The laser device produces an invisible treatment beam for surgery and a visible aiming beam. The pulsed Nd:YAG treatment beam is an invisible beam of light (1064 nanometer wavelength); a Helium-Neon (HeNe) laser within the laser head console supplies the red aiming beam. The laser energy is developed inside an optical resonant cavity. A crystal rod of neodymium-doped Yttrium Aluminum Garnet (pulsed Nd:YAG) is placed between two mirrors. The rod is "pumped" by a flashlamp that excites the Neodymium ions in the YAG crystal. Once excited, stimulated emission of photons occurs. Laser energy exits the cavity through a partially transmitting mirror and enters the distal end of the contact fiber-optic cable at the aperture. The laser energy is transmitted though the fiber-optic cable and exits the proximal tip of the fiber. The device is controlled by microprocessor via keyboard access by the operator, which allows various settings for energy levels, pulse widths and repetition rates. Software controls preclude emission of laser energy in any of a number of fault conditions.

Summary Rationale: The SunLase 800P is a free running Nd:YAG laser based on the same technology as the predicate Nd:YAG lasers listed above. In addition, the predicate diode laser devices listed above operate clinically in substantially equivalent fashion; their operational technology differs only by source of emission, pulse rate, and wavelength. Tissue effects by predicate Nd:YAG and diode devices exhibit identical physical characteristics. As such, the indications for use and intended uses are the same. This consolidation of clinical applications presents no new safety issues.

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Intended Uses: The following are the oropharangeal indications for use for which the device will be marketed:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis
- Implant recovery
- Incision and drainage of abscess
- Laser Assisted Uvulopaletoplasty (LAUP)
  This laser is effective for cutting, ablating, coagulating and removing oropharangeal soft tissue that has been diagnosed as anatomically abnormal or naturally occurring hypertrophic which has been identified and confirmed as being associated with chronic palatal snoring.
- Leukoplakia
- Operculectomy
- Oral Papillectomies
- Pulpotomy and Pulpotomy as an adjunct to root canal therapy
- Reduction of denture hyperplasia
- Reduction of gingival hypertrophy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal therapy
- Removal of post-surgical granulations
- Selective ablation of enamel (First Degree Caries Removal)
- Soft tissue crown lengthening
- Sulcular debridement or soft tissue curettage (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Tissue retraction for impression
- Treatment of Apthous ulcers
- Vestibuloplasty

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Thomas H. Louisell
Director, Regulatory Affairs
and Quality Systems
Lares Research, Inc.
295 Lockheed Avenue
Chico, California 95973

Re: K011960
Trade/Device Name: SunLase 800P Laser System (to be sold as "Pocket Pro®" or PocketPro S4®
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 28, 2001
Received: October 5, 2001

Dear Mr. Louisell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER: K011960

DEVICE NAME: SunLase 800P Laser System (to be sold as "PocketPro®" or "PocketPro S4®"

INDICATIONS FOR USE:

The SunLase 800P laser device is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. The device is indicated for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact, fiber-optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, dermatology and plastic surgery. The following are the oropharangeal indications for use for which the device will be marketed:

- Excisional and incisional biopsies
- Excision and vaporization of herpes simplex I and II
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
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- Vestibuloplasty

Signature : Thomas H. Louisell

Name : Thomas H. Louisell
Title : Director - Regulatory Affairs & Quality Systems
Date : 17 May 2001

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011960